

Overview of EPA's Activities on Trichloroethylene under the Toxic Substances Control Act (TSCA)

**TCE Roundtable
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Dr. Stan Barone and Toni Krasnic
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency



Overview

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act
- Evaluating Risks of Existing Chemicals
- Initial 10 Chemicals
- TCE Overview
- TCE Risk Evaluation
- TSCA § 6(a)
- Important Dates
- Additional Information

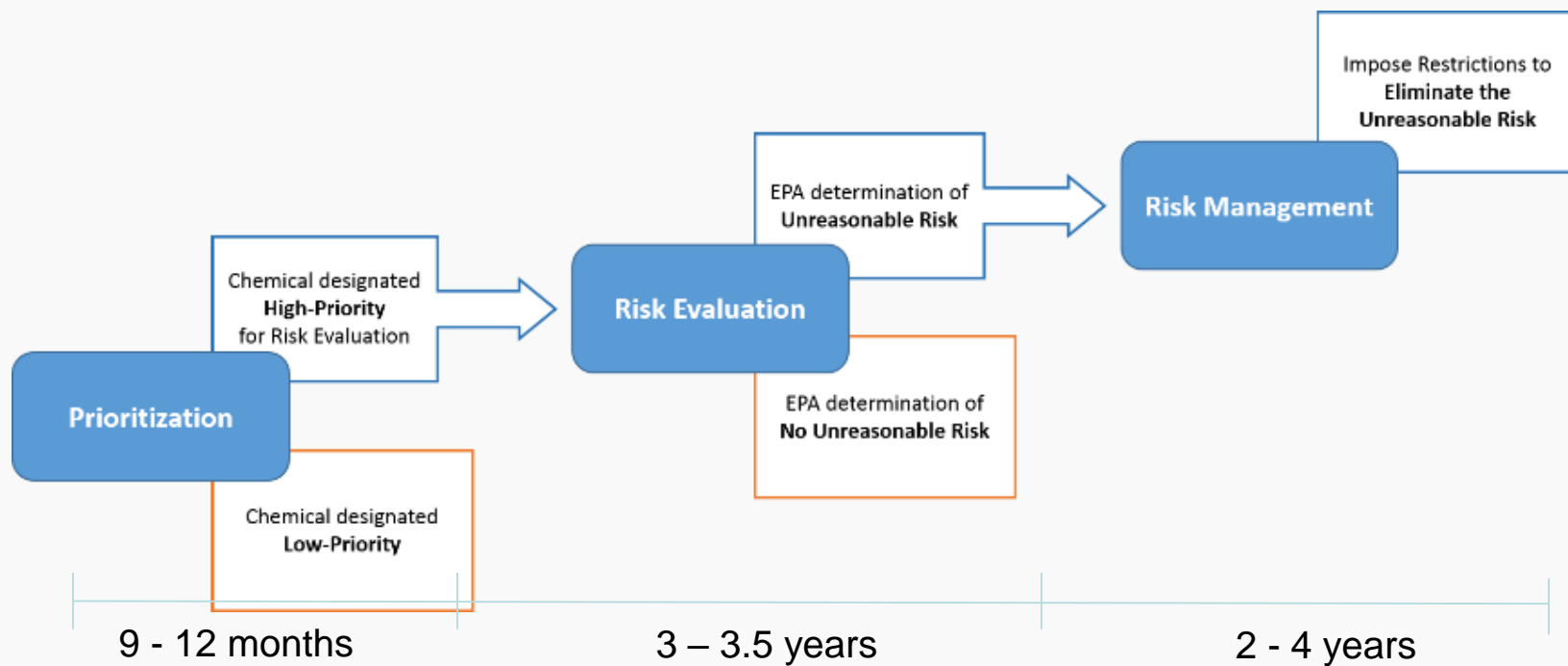


The New Chemical Safety Law

- The “Frank R. Lautenberg Chemical Safety for the 21st Century Act” was signed by the President going into immediate effect on June 22, 2016
- Amends and updates the Toxic Substances Control Act of 1976
- Passed by large bipartisan margins in the U.S. House (403 to 12) and unanimously in Senate
- Received support from chemical industry and downstream users of chemicals, NGOs and other stakeholders



Evaluating Risks of Existing Chemicals





Risk Evaluation: *Statutory Requirements*

- EPA has established by rule a process for risk evaluation
 - Risk evaluations will determine if a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use
 - Without consideration of cost or other non-risk factors
 - Including unreasonable risk to potentially exposed or susceptible subpopulations
- This process must be completed within 3 – 3.5 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical substance
- By December 2019, EPA must have designated at least 20 chemical substances as High-Priority for risk evaluation and 20 chemical substances as Low-Priority
 - Additional risk evaluations may come from manufacturer requests



Risk Evaluation: *Statutory Requirements*

- Scope documents – published within 6 months of initiation
 - Must identify hazards, exposure, conditions of use, potentially exposed or susceptible subpopulation(s)
- Draft Risk Evaluation
 - Integrate and assess reasonably available information on hazards and exposures for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations
 - Publication in Federal Register
 - At least 30-day public comment period
- Final Risk Evaluation – published within 3-3.5 years of initiation
 - Publication in Federal Register
- Science Requirements
 - EPA is required to meet the scientific standards in TSCA for best available science, utilizing a weight-of-scientific-evidence approach when conducting risk evaluations



Initial 10 Chemical Substances

- EPA identified the initial 10 chemical substances and formally initiated risk evaluations on December 19, 2016
 - Statute required chemical substances be drawn from the 2014 Update to TSCA Work Plan
 - Methodology involved screening for hazard, exposure, persistence, and bioaccumulation

1,4-Dioxane

1-Bromopropane

Asbestos

Carbon Tetrachloride

Cyclic Aliphatic Bromide Cluster
(HBCD)

Methylene Chloride

N-methylpyrrolidone (NMP)

Pigment Violet 29

Tetrachloroethylene, or perchloroethylene (perc)

Trichloroethylene (TCE)



TCE: Overview

- Volatile organic compound (VOC) and hazardous air pollutant (HAP) classified as a human carcinogen
- Widely used in industrial and commercial processes; there are some uses in consumer products
- More than 255 million lbs per year used in the United States
 - Majority of TCE (~84%) used as an intermediate for manufacturing refrigerant chemicals
 - Much of the remainder used as a solvent for metal degreasing (~15%)
 - A small percentage (~1%) used in other applications, including dry cleaning and consumer uses



TCE: Uses

- Industrial and commercial uses include:
 - Manufacturing
 - Processing as a reactant
 - Degreaser/cleaner (vapor, cold cleaning, aerosol)
 - Intermediate in refrigerant manufacture
 - Adhesive, sealants, paints, and coatings
 - Spot cleaning in dry cleaning facilities
 - Others
- Consumer uses include:
 - Degreaser/cleaner
 - Lubricant
 - Spot remover
 - Carpet cleaner
 - Adhesive/sealant
 - Others



TCE Risk Evaluation

- In 2014, before the TSCA amendment by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA identified risks with TCE uses for aerosol degreasing, spot cleaning in dry cleaning facilities, and vapor degreasing. Note that EPA will be re-evaluating these uses.
 - These conditions of use will be part of EPA’s determination of whether TCE presents an unreasonable risk “under the conditions of use,” TSCA § 6(b)(4)(A) as part of EPA’s current risk evaluation



TCE Risk Evaluation (continued)

- TCE Problem Formulation
 - Published on June 1, 2018: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/trichloroethylene-tce-problem-formulation>
 - Refines the scope, specifically the conditions of use considered in the risk evaluation
 - Describes uses that EPA expects to evaluate and describes how EPA expects to conduct the evaluations
- TCE Risk Evaluation
 - Risk evaluations will focus on those exposure pathways associated with TSCA uses that are not subject to existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes because these pathways are likely to represent the greatest areas of concern
 - Risk evaluations will determine if a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use
 - Each draft risk evaluation will be peer reviewed
 - At least 30-day public comment period
 - EPA expects to publish draft Risk Evaluations by December 2019
 - EPA expects to publish final Risk Evaluations by June 2020



TSCA § 6(a)

- Provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture
- EPA must:
 - Conduct a risk evaluation to determine whether a chemical substance or mixture “presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use” TSCA § 6(b)(4)
 - Apply one or more of the regulatory options to the extent necessary so that the chemical substance no longer presents such risk



Options Under TSCA § 6(a)

- Prohibit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit or otherwise restrict for particular use or above a set concentration
- Require minimum warnings and instructions
- Require recordkeeping or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal
- Direct manufacturers/processors to give notice of risk to distributors and users and replace or repurchase



Importance of Information and Dialogue

- Information is important for understanding conditions of use and informing risk evaluations
 - Use and exposure information
 - Risk evaluation



Important Dates

- Problem Formulation documents were published on June 1, 2018
 - Refines the scope, specifically the conditions of use considered in the risk evaluation
- Draft Risk Evaluations
 - Risk evaluations will determine if a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use.
 - Each draft risk evaluation will be peer reviewed
 - At least 30-day public comment period
 - EPA expect to publish draft Risk Evaluation by December 2019
- EPA expects to publish final Risk Evaluations by June 2020



Additional Information

- Contacts:
 - Toni Krasnic, 202-564-0984, krasnic.toni@epa.gov
- EPA Website
 - Problem Formulation for TCE Risk Evaluation: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/trichloroethylene-tce-problem-formulation>
 - Risk Evaluation for TCE: www.epa.gov/assessing-and-managing-chemicals-under-tsca/trichloroethylene-tce
 - Risk Management for TCE: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0>
 - EPA's TSCA Implementation Activities website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Dockets (www.regulations.gov)
 - Trichloroethylene; TSCA Review and Scoping: [EPA-HQ-OPPT-2016-0737](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0737)
 - TCE Rulemaking under TSCA Section 6(a) for Use of TCE in Vapor Degreasing: [EPA-HQ-OPPT-2016-0387](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0387)
 - Rulemaking under TSCA Section 6(a) for Use of TCE in Aerosol Degreasing and Spot Cleaning in Dry Cleaning Facilities: [EPA-HQ-OPPT-2016-0163](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0163)
 - Significant New Use Rule (SNUR) for TCE in Consumer Products: [EPA-HQ-OPPT-2014-0697](https://www.regulations.gov/docket/EPA-HQ-OPPT-2014-0697)
 - TCE Workshop (July 29-30, 2014): [EPA-HQ-OPPT-2014-0327](https://www.regulations.gov/docket/EPA-HQ-OPPT-2014-0327)
 - TCE Risk Assessment (2014): [EPA-HQ-OPPT-2012-0723](https://www.regulations.gov/docket/EPA-HQ-OPPT-2012-0723)